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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,066	03/23/2007	Erika Jensen-Jarolim	37488.00800US	9617

38647 7590 04/23/2010

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EXAMINER	
ROONEY, NORA MAUREEN	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
04/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,066	JENSEN-JAROLIM ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-190* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Claims 1-19 are pending.

2. Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)). For examination purposes "use" claims are interpreted as a method of the first recited "use".

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-17, directed to microspheres for allergy therapy containing antigens and/or DNA of antigens, characterized in that the microspheres have a binding constant KB of at least l x 10^4 M^{-1} toward the specific carbohydrate residue of intestinal and/or nasal epithelial cells.

II. Claim 34, directed to a method for producing microspheres for allergy therapy containing antigens and/or DNA of antigens, characterized in that the microspheres have a binding constant

KB of at least l x 10^4 M^{-1} toward the specific carbohydrate residue of intestinal and/or nasal epithelial cells, characterized in that the microspheres are first loaded with antigens and/or DNA of antigens, and the microspheres are then functionalized.

III. Claim 35, directed to a method for using microspheres for allergy therapy containing antigens and/or DNA of antigens, characterized in that the microspheres have a binding constant KB of at least l x 10^4 M^{-1} toward the specific carbohydrate residue of intestinal and/or nasal epithelial cells for allergy therapy.

5. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defines the contribution over the prior art of Clark et al. (IDS filed on 01/06/2006) as evidenced by the specification on pages 13-16.

Clark et al. teaches PLG (PLGA) microspheres containing antigens characterized in that the microspheres have lectins, such as WGA, on their surface that increase the adhesion to mucosal cells of the intestinal and nasal epithelium (In particular, Table 1, page 208, pages 212-217, whole document).

The specification teaches on pages 13-16 that PLGA microspheres with WGA lectin on the surface are encompassed by the instant claim recitations. Therefore, without evidence to the contrary, the recitation of "a binding constant KB of at least $1 \times 10^4 M^{-1}$ toward the specific carbohydrate residue of intestinal and/or nasal epithelial cells" is inherent in the reference PLG microspheres with WGA lectin on the surface.

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "for allergy therapy" of claim 1 does not carry patentable weight per se. The claims read on the active or essential ingredients of the composition and a composition is a composition irrespective of its intended use. It is noted that the specification does not provide any limiting definition of microspheres for allergy therapy. Therefore, the reference PLG (PLGA) microspheres containing antigens characterized in that the microspheres have lectins, such as WGA, on their surface that increase the adhesion to mucosal cells of the intestinal and nasal epithelium are encompassed. Giving the terms their broadest reasonable definition, PLG (PLGA) microspheres containing antigens characterized in that the microspheres have lectins, such as WGA, on their surface that increase the adhesion to mucosal cells of the intestinal and nasal epithelium are not incompatible with use for allergy therapy.

The reference teachings anticipate the claimed invention.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention. The election of an invention may be made with or without traverse. To reserve a right

to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is

571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 21, 2010
Nora M. Rooney
Patent Examiner
Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644